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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,260	12/09/2005	Dorotea Raventos Segura	10328.204-US	9630

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NOVOZYMES NORTH AMERICA, INC.
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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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04/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,260	Applicant(s) SEGURA ET AL.	
	Examiner CHIH-MIN KAM	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/9/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-7, 13-16 and 24-26, and SEQ ID NO:3 in the response to restriction requirement filed January 9, 2009 is acknowledged. In the amendment filed January 9, 2009, claims 1-16, 21 and 24-26 have been cancelled, and new claims 27-39 have been added. Regarding the selection of one amino acid sequence, this requirement is traversed by applicants on the ground(s) that the present invention is directed to antimicrobial peptides, compositions comprising same, and methods of using same, where the polypeptides are defined by an amino acid sequence, and are structurally related. Therefore, the claims satisfy the unity of invention requirement. Furthermore, no objection to unity of invention was raised at any point of the PCT prosecution. Applicants' response has been considered, and the arguments are found persuasive, thus the requirement for sequence selection is withdrawn. Therefore, claims 27-39 and all the sequences are examined.

Informalities

The disclosure is objected to because of the following informalities:

2. The specification recites amino acid sequences, for example, at pages 1, 4, 5 and 6 without providing sequence identifiers "SEQ ID NO:". One of the sequences, G-X₁-X₂-X₃-R-X₄-X₅-X₆-K-I-X₇-X₈-K-X₉-X₁₀-K-X₁₁-X₁₂-Z is not listing in the Sequence Listing. Applicant must comply with the requirements of sequence rules (37 CFR 1.821-1.825) to include all the sequences in the sequence listing. Appropriate correction is required.

Claim Objections

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3. Claim 28 is objected to because the claim recites an amino acid sequence of G-X₁-X₂-X₃-R-X₄-X₅-X₆-K-I-X₇-X₈-K-X₉-X₁₀-K-X₁₁-X₁₂-Z without providing a sequence identifier “SEQ ID NO:”. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 27-38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is directed to a polypeptide. As written, the claim does not explicitly indicate the hand of man. Insertion of “isolated” or “purified” in connection with the polypeptide in claims 27 and 28 is suggested. See MPEP § 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 28-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 28-31 are directed a polypeptide having antimicrobial activity comprising an amino acid sequence, which differs by at the most two amino acids from the amino acid

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sequence G-X₁-X₂-X₃-R-X₄-X₅-X₆-K-I-X₇-X₈-K-X₉-X₁₀-K-X₁₁-X₁₂-Z, where each variable is defined in the claims, where the amino acids in the polypeptides are D or L forms.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The specification indicates the polypeptide of the invention may be artificial variant which comprises an amino acid sequence that has at the most two substitutions, deletions and/or insertions of amino acids as compared to the amino acid sequence of G-X₁-X₂-X₃-R-X₄-X₅-X₆-K-I-X₇-X₈-K-X₉-X₁₀-K-X₁₁-X₁₂-Z, or amino acids 1 to 29 of anyone of SEQ ID NO:1 to SEQ ID NO:57, or amino acids 1 to 19 of anyone of SEQ ID NO:58 to SEQ ID NO:69, and in one embodiment of the invention, the amino acid changes are conservative amino acid substitutions

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that do not significantly affect the folding and/or activity of the protein (page 7, line 29-page 8, line 16). However, the specification does not describe which two residues in the polypeptides are substituted, deleted and/or inserted, thus, the whole genus of polypeptides with two different amino acids from G-X₁-X₂-X₃-R-X₄-X₅-X₆-K-I-X₇-X₈-K-X₉-X₁₀-K-X₁₁-X₁₂-Z, SEQ ID NO;1, 2 or 58 would contain numerous amino acid sequences. Furthermore, there are no examples on these polypeptide variants. Since there is no structure-activity correlation for these polypeptide variants, a skilled artisan cannot predict which polypeptide variant is functional. The lack of description on the structure-activity correlation for the polypeptide variants and lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 is indefinite since the claim lacks essential steps in the method for killing or inhibiting growth of microbial cells. The missing steps are an effective amount of the polypeptide administered and the outcome of the method.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Tossi *et al.* (Eur. J. Biochem. 250, 549-558 (1997), listed in IDS filed 12/9/2005).

Tossi *et al.* teach an antimicrobial peptide of PGG peptide with the amino acid sequence of GLLRRLRKKIGEIFKKYG (Table 1), which is different from the sequence of G-X₁-X₂-X₃-R-X₄-X₅-X₆-K-I-X₇-X₈-K-X₉-X₁₀-K-X₁₁-X₁₂-Z, where X₁, X₂ and X₄ each is L, X₃ and X₅ each is R, X₆ and X₁₀ each is K, X₇ is G, X₈ is E, X₉ is F, X₁₁ is Y, X₁₂ is G, and Z is R, by two amino acids at positions 13 and 19 (claim 28).

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

April 23, 2009